Supreme Court, U.S.
FILED
MAR 1 1996
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(4) (5)

Nos. 95-754, 95-886

In the

Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondent/Cross-Petitioners.

On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

BRIEF FOR CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

ROBERT L. COWLES
DANIEL C. SHAUGNESSY
COWLES & SHAUGNESSY
Suite 901
233 East Bay Street
Jacksonville, FL 32202
(904) 359-9500

ROBERT F. SPOHRER
SPOHRER, WILNER & MAXWELL
444 East Duval Street
Jacksonville, FL 32202
(904) 354-8310

BRIAN WOLFMAN
(Counsel of Record)
ALLISON M. ZIEVE
ALAN B. MORRISON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, N.W.
Washington, D.C. 20009
(202) 588-1000

LAURENCE H. TRIBE
Hauser Hall 420
1475 Massachusetts Avenue
Cambridge, MA 02138
(617) 495-4621

Attorneys for Cross-Petitioners

March 1, 1996

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law tort claims to recover money damages for injuries caused by a defective medical device?

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BRIEF FOR CROSS-PETITIONERS
LORA LOHR AND MICHAEL LOHR

OPINIONS BELOW

The opinion of the court of appeals is reported at 56 F.3d 1335 (11th Cir. 1995), and is reproduced in the appendix to the petition in No. 95-754 ("Pet. App.") at 1a. The unreported opinion of the United States District Court for the Middle District of Florida is reproduced at Pet. App. 1b.

JURISDICTION

The judgment of the court of appeals was entered on July 3, 1995. Cross-respondent filed a timely petition for rehearing and suggestion for rehearing in banc on July 24, 1995, which the court of appeals denied on August 15, 1995 (Pet. App. 1e). The petition for writ of certiorari in No. 95-754 was filed on November 13, 1995, and the cross-petition was filed on December 6, 1995. The Court granted the petition and the cross-petition on January 19, 1996. This Court has jurisdiction under 28 U.S.C. § 1254(1) and Rule 12.5 of this Court.

STATUTES AND REGULATIONS INVOLVED

The principal statutes and regulations involved in this case are reproduced in the appendix to this Brief ("App.").

STATEMENT OF THE CASE

Approximately five years ago, a pacemaker manufactured by cross-respondent Medtronic, Inc., and implanted in cross-petitioner Lora Lohr, failed suddenly, causing injuries to Ms. Lohr and requiring her to undergo emergency surgery. Pet. App. 6a. The question presented is whether cross-petitioners are entitled to seek compensation for their injuries under Florida common law, or whether, as Medtronic maintains, a federal law enacted in 1976, for the purpose of protecting consumers from potentially dangerous medical devices, was intended to bar their access to their state tort systems entirely.

A. The Basic Structure Of The Medical Device Amendments.

1. Legislative Background.

Under federal law, a "medical device" includes a vast array of products, such as tongue depressors, band-aids, tampons, bone screws, hip replacements, artificial heart valves, and pacemakers. *See* 21 U.S.C. § 321(h). Prior to 1976, medical devices were largely unregulated. Although the Food and Drug Administration ("FDA") had limited authority to seize adulterated and misbranded devices already on the market, it lacked the authority to prevent the entry of a medical device on the market that it had had for many years with respect to drugs. *See* H.R. Rep. 853, 94th Cong., 2d Sess. 8-10 (1976)("*House Report*"); *see id.* at 11 (a "serious drawback of the existing authority is that FDA cannot act against a hazardous medical device until after it is on the market").

By the mid-1970's, the peril of this regulatory gap had become clear. There had been a series of public health hazards caused by dangerous devices. Most notable was the defectively designed Dalkon Shield intrauterine device, which had entered the market without regulatory scrutiny and had caused numerous deaths and thousands of serious injuries to otherwise healthy women. *See House Report*, at 8; S. Rep. 33, 94th Cong., 1st Sess. 1-2, 6-7, *reprinted in* 1976 U.S.C.C.A.N. 1070-72, 1075-76.

In 1976, responding to the preventable harms caused by such devices, *id.*, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. Pub. L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. § 360c *et seq.*). The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous devices and providing a structure through which devices would reach the market. *See House Report*, at 1-12. Congress placed authority for implementing the MDA in the Secretary of Health, Education, and Welfare (now Health and Human Services), who delegated that responsibility to the FDA. *Id.* at 13.

2. Device Classification.

Under the MDA, each medical device falls into one of three classes, depending on its medical importance and its potential for causing harm to patients. *House Report*, at 34. Class I devices, such as tongue depressors, are those for which the MDA's "general controls" applicable to all devices, such as recordkeeping and good manufacturing guidelines, *see* 21 U.S.C. §§ 360i(a), 360j(f), are sufficient to provide reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(A).

Class II devices, such as tampons, 21 C.F.R. § 874.3300(b)(2), are those for which general controls alone are insufficient to protect public health. *See* 21 U.S.C. § 360c(a)(1)(B). Although the statute originally required the FDA

to promulgate performance standards for Class II devices, not a single standard was ever issued. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 523 & n.82 (1988); S. Rep. 513, 101st Cong., 2d Sess. 15 (1990). Thus, in 1990, Congress amended the MDA to make Class II devices subject to "special controls," which may include, in the FDA's discretion, performance standards, post-market surveillance, patient registries, and other measures deemed appropriate by the FDA. Pub. L. No. 101-629, § 5(a), 104 Stat. 4517-18 (1990); *see* 21 U.S.C. § 360c(a)(1)(B).

Finally, Class III devices are those which operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). In theory, Class III devices must undergo premarket approval ("PMA") by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA. *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The manufacturer's PMA application must also contain proposed labeling for the device, a sample of the device, and other information. *See generally id.* The FDA may grant premarket approval only if it finds that there is "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2).

3. Exceptions To The Premarket Approval Process.

The PMA process does not apply to the vast majority of devices because of two related exceptions. First, a device on the market prior to the effective date of the 1976 Act—a so-called "grandfathered" device—was not required to undergo premarket approval, even if it was a Class III type of device. *See, e.g.*, 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Manufacturers

of pre-MDA devices do not have to seek premarket approval until 30 months have passed since the FDA classified the device in Class III, *and* 90 days have elapsed since the FDA's issuance of a final regulation calling for PMA applications for that specific type of device. 21 U.S.C. §§ 360e(b), 351(f)(2)(B).

Second, a device marketed *after* the MDA's effective date—such as the pacemaker implanted in Lora Lohr (*see* Pet. App. 6a)—may bypass the PMA process if the device is "substantially equivalent" to either a "grandfathered" pre-MDA device, or a Class I or Class II device. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A). This exception to premarket approval, known as the "510(k)" process, simply requires the manufacturer to notify the FDA under section 510(k) of the Act of its intent to market the device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA "predicate device." 21 U.S.C. § 360(k); *see id.* § 360c(f)(1). The 510(k) process is much less expensive than obtaining a PMA and has other marketing advantages as well. *See* Pet. App. 19a n.14 (*citing* Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1, 47 & n.273 (1989)).[1]

Section 510(k) notifications are required for most Class I and Class II devices, but premarket approval is not a part of the statutory design for those devices. With respect to Class III devices, however, substantial equivalence was intended as a stop-gap measure, so that companies that sold grandfathered devices did

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[1] *See also* Adler, *supra*, 43 Food Drug Cosm. L.J. at 516 ("A 510(k) notification requires little information, rarely elicits a negative response from FDA, and gets processed very quickly"); Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510, 515-18 (1984)(describing the substantial marketing advantages of section 510(k) over PMA in terms of having to provide far less information to FDA, significantly higher FDA allowance rates, and speed of disposition).

not gain a competitive advantage during the period in which the FDA classified devices and implemented the statute, after which both pre- and post-MDA Class III devices would be required to undergo PMA. Kahan, *supra*, 39 Food Drug Cosm. L.J. at 514-15; Adler, *supra*, 43 Food Drug Cosm. L.J. at 513; *see House Report*, at 30; S. Rep. 513, *supra*, at 14-15. In fact, the FDA has not yet required PMAs for most Class III devices, and over 80 percent of them—including critical devices, such as pacemakers—enter the market *without* premarket approval (*i.e.*, as substantial equivalents to grandfathered devices). H.R. Rep. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. Significantly, unlike the PMA process, the 510(k) notification process does not call for scrutiny of a device's safety and effectiveness. *Compare* 21 C.F.R. § 814.45(c)(PMA), *with id.* § 807.100(b)(510k).

4. State Regulatory Efforts And Preemption Under the MDA.

During the MDA enactment process, Congress was informed of state regulatory programs, most notably in California, that had stepped into the federal regulatory vacuum and required that devices undergo premarket approval before their commercial distribution. *House Report*, at 45 (noting that California required PMA for intrauterine devices). Concluding that state premarket scrutiny, even if not uniform, was preferable to no premarket scrutiny at all, Congress crafted a provision that would permit state regulatory programs to remain in place until the FDA had implemented specific counterpart federal regulations, but thereafter would preempt conflicting state and local regulatory measures. *Id.* Thus, 21 U.S.C. § 360k(a) provides that States may not "establish or continue in effect with respect to a device ... any requirement" that is "different from, or in addition to" certain federal device "requirements" issued under the MDA. 21 U.S.C. § 360k(a)(reproduced in App. 1a). Even then, Congress authorized

the FDA to grant state and local governments exemptions from preemption for their medical device laws in certain circumstances. *See* 21 U.S.C. § 360k(b)(discussed *infra* at 23-27).

B. Facts.

This case involves injuries caused by a Medtronic pacemaker and its related components, including the lead, which is a wire connected to the pacemaker that delivers the electrical impulse to the heart. *See* Pet. App. 6a; 21 C.F.R. § 870.3680(b)(describing "permanent pacemaker electrode"). Although pacemaker leads were classified as Class III devices more than 16 years ago, 45 Fed. Reg. 7943, 7945 (Feb. 5, 1980), the FDA has never issued a regulation under 21 U.S.C. § 360e(b) calling for PMA applications for such devices. *See* 21 C.F.R. § 870.3680(c)("No effective date has been established of the requirement for premarket approval" for pacemaker leads). The particular lead in question is Medtronic's Model 4011. R1-37, Ex. 1, ¶ 6.[2]

On October 20, 1982, Medtronic notified the FDA of its intent to market the Model 4011. R1-37, Ex. 1, at Ex. A.[3] In a letter issued 40 days later, the FDA stated that the device had been found substantially equivalent to a pre-MDA device. *Id.* The FDA told Medtronic that it could market the device subject only to the Class I "general controls" applicable to all devices. *Id.*

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[2] Record citations in the form "R1-37" refer to the district court record. The first figure refers to the volume number of the record, the second refers to a particular document by docket number, and the third reference, if any (*e.g.*, Ex. 1), refers to a specific portion of that document.

[3] Letter from Robert G. Britain, Associate Director for Device Evaluation, Office of Medical Devices, National Center for Devices and Radiological Health, Food and Drug Administration, to Edward W. Numainville, Product Regulation Manager, Medtronic, Inc. (Nov. 30, 1982)(reproduced in App. 10a).

The FDA emphasized that "this letter does not in any way denote official FDA approval of your device," and warned the company about creating any "misleading" impression to the contrary. *Id.* Thus, the Model 4011 lead reached the market solely on the basis of its substantial equivalence to devices that themselves were never evaluated for safety and effectiveness. As a government report specifically analyzing the repeated failures of Medtronic's pacemaker leads explained:

> As of 1984, 15 new Medtronic polyurethane-insulated pacemaker leads had been marketed since the first was introduced in 1977. Because each new lead was determined to be "substantially equivalent" to a previously marketed lead ... each one "piggybacked" on its predecessors through FDA's 510(k) review process. This process does not require FDA to determine that any of these models are safe and effective — and FDA has not done so.

U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks are Still High* 1 (GAO/PEMD-92-20 Sept. 1992).

In January 1987, cross-petitioner Lora Lohr was implanted with a Medtronic pacemaker, including the 4011 lead. On December 30, 1990, Ms. Lohr's pacemaker failed, resulting in a "complete heart block," which required her to undergo emergency surgery and replacement of her pacemaker. Complaint ¶¶ 4, 7, Eleventh Circuit Record Excerpts ("RE") 7, 8. Her treating physician attributed the pacemaker failure to a defect in the lead. Pet. App. 6a; *see* Dep. of Robert L. Pekaar, M.D., at 13, 26-28 (Sept. 8, 1993), R1-28 (exhibit folder).

C. Proceedings And Decisions Below.

Cross-petitioners Lora and Michael Lohr filed this case on March 9, 1993, in Florida state court. The complaint alleged that Medtronic had designed, manufactured, and assembled its

pacemaker in an unreasonably dangerous manner and that the pacemaker was prone to sudden, catastrophic failure. The complaint further alleged that Medtronic had failed to warn Ms. Lohr or her physicians of the product's tendency to life-threatening failure, despite Medtronic's knowledge of other prior failures. As a result of the pacemaker's failure, Ms. Lohr suffered pain, scarring, physical handicap, and mental suffering, and sought compensation for those injuries, as well as for future expenses to be incurred in restoring her health. Michael Lohr, Lora Lohr's husband, claimed loss of consortium based on his wife's injuries. Complaint, ¶¶ 8, 9-14, RE 8-9.

Medtronic removed the case to the United States District Court for the Middle District of Florida under 28 U.S.C. § 1441 on the basis of diversity of citizenship. Pet. App. 6a. It then filed a motion for summary judgment on the ground that the Lohrs' tort claims were preempted by 21 U.S.C. § 360k(a), the MDA provision which concerns state-law "requirements" that are "different from, or in addition to" certain federal requirements established under the MDA. Pet. App. 7a. The district court denied the motion, holding that the Lohrs' common-law claims would not pose an obstacle to the objectives of the MDA. Pet. App. 5d. The court subsequently reversed itself and granted summary judgment to Medtronic in light of the Eleventh Circuit's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (1994)(per curiam), which the district court interpreted as requiring preemption of all product liability claims concerning a medical device. Pet. App. 2b.

The Eleventh Circuit reversed in part and affirmed in part. It began by noting that, under its *per curiam* decision in *Duncan*, section 360k(a) preempted at least *some* common-law tort claims. Pet. App. 11a. The court of appeals also ruled that the section 510(k) process, because it merely "grandfathers" onto the market devices that are similar to pre-MDA devices, does not itself establish preemptive "requirements." Pet. App. 27a ("the 510(k)

process is focused on equivalence, not safety"). The court further held that there were no MDA requirements relating to device design applicable to the pacemaker leads that could be said to preempt the Lohrs' design-defect claim under section 360k(a). Pet. App. 26-29a.

However, the Eleventh Circuit also held that the Lohrs' failure-to-warn and manufacturing-defect claims were preempted, not on the basis of specific MDA requirements relating to warnings for, or the manufacture of, pacemaker leads, but on the basis of the FDA's regulations pertaining to prescription device labeling and good manufacturing, which are applicable to medical devices generally. Pet. App. 29a-32a. To reach that result, the court relied on an FDA regulation which, as a prerequisite to preemption of a state device requirement under section 360k(a), demands that there be a "specific counterpart [FDA] regulation[]" or "other specific requirement[] applicable to a particular device under the act...." 21 C.F.R. § 808.1(d). In doing so, the court rejected the Lohrs' claim that, under section 808.1(d), the federal requirement must be specific to the particular type of device—here, pacemaker leads—in order to trigger preemption under section 360k(a). Pet. App. 20a-21a.

Finally, despite the language of section 360k(a), which preempts only those state and local requirements that are "different from, or in addition to" requirements under the MDA, the court of appeals held that the Lohrs' manufacturing-defect and failure-to-warn claims would be preempted even if they sought only to enforce the federal MDA requirements in those areas. The court found one of its prior preemption rulings controlling on that issue. *See* Pet. App. 13a (*citing Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993)).

SUMMARY OF THE ARGUMENT

Medtronic's position is that 21 U.S.C. § 360k(a) grants device manufacturers a blanket tort immunity. This view is at

odds with the MDA's text, structure, history, and purpose, and with authoritative FDA regulations concerning the scope of MDA preemption. Nowhere in the MDA or its legislative history did Congress so much as hint, let alone express in "clear and manifest" terms, *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985), that the Act comprehensively abolished state common-law remedies historically available to injured medical device users. Against the backdrop of a series of public health tragedies in which patients died or were seriously injured by defective medical devices, Congress enacted the MDA "to assure the[ir] safety and effectiveness." Conference Report, H.R. Rep. 1090, 94th Cong. 2d Sess. 1 (1976). It is unthinkable that Congress would have left injured medical device consumers with no means of obtaining compensation for their injuries, and with significantly *less* protection than they had prior to the MDA's enactment.

I. Under 21 U.S.C. § 360k(a), a State may not "establish or continue in effect with respect to a medical device" a "requirement" that is "different from, or in addition to" certain "requirements" "applicable to" a medical device under the MDA. The term "requirement" in section 360k(a) encompasses only positive law, such as statutes and regulations, rather than damages actions, and thus does not reach the Lohrs' claims for compensation under Florida common law.

Section 360k(a) refers once to state-law "requirements" that are candidates for preemption and twice to federal "requirements" that may have preemptive effect. The federal "requirements" flow solely from positive law—the MDA and its regulations. To interpret state-law "requirements" as including actions for damages would thus run counter to the basic rule of statutory construction that multiple uses of the same word in the same statute should be accorded the same meaning. *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). The MDA's legislative history confirms this view, as it refers to the statute's state-law requirements as "regulations," a

term which does not include common law, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 519 (1992), and mentions only positive enactments of state legislatures as candidates for preemption. H.R. Rep. 853, 94th Cong., 2d Sess. 45-46 (1976).

Further, section 360k(a) preempts only state-law requirements "with respect to a device." Unlike state statutory or regulatory requirements which tell device manufacturers how to produce their devices, the general common-law duties under which the Lohrs seek compensation are not requirements "with respect to a device" under section 360k(a). Rather, if the Lohrs prevail at trial, Medtronic will be obligated only to pay damages, but it will not be *required* to do anything with "respect to [the] device."

Two other MDA provisions further demonstrate that the common law is beyond the reach of section 360k(a). First, 21 U.S.C. § 360k(b) permits the FDA to grant states exemptions from preemption for any state "requirement" that is preempted under section 360k(a). Subsection (b), however, does not apply to damages claims, as shown both by its text and the FDA's implementing regulations. For example, the FDA's regulations—which are entitled to deference—contemplate exemptions only for "any statute, rule, regulation or ordinance" that a state has "enacted." 21 C.F.R. §§ 808.20(a), 808.20(c)(1). Thus, the presence of subsection (b) in the statute bolsters the conclusion that section 360k(a) does not apply to damages actions. *See Rake v. Wade*, 113 S. Ct. 2187, 2193 (1993).

Second, 21 U.S.C. § 360h(d) provides that, even where the FDA orders a manufacturer to repair or replace a faulty medical device, compliance with the order "shall not relieve" the manufacturer "from liability under ... State law." This provision shows that Congress understood that the MDA and state tort law would coexist, and that it did not intend the enactment of landmark consumer protection legislation to immunize medical device manufacturers from product liability actions.

II. Quite apart from whether 21 U.S.C. § 360k(a) can, under some circumstances, preempt common-law claims, the claims in this case are not preempted because there are no preemptive federal requirements "applicable to" the pacemaker lead implanted in Lora Lohr. Under section 360k(a), state law concerning medical devices may be preempted only if there are device-specific federal requirements, either in the MDA itself or in regulations issued by the FDA, that directly conflict with the requirements established under state law. *See also* 21 C.F.R. § 808.1(d).

Medtronic's pacemaker lead entered the market through the MDA's 510(k) notification procedures, under which Medtronic marketed the device based on its substantial equivalence to a device that was grandfathered onto the market when the MDA was enacted in 1976. *See* 21 U.S.C. § 360(k); 21 C.F.R. § 807.87. That process did not establish any requirements pertaining to the device's safety and effectiveness—much less any such requirements that conflict with the Lohrs' common-law claims. *See id.* § 807.97. Moreover, because there are no specific manufacturing or labeling requirements applicable to the device, there is no preemption of the Lohrs' damages claims, which are premised on defective manufacture of the device and Medtronic's failure to warn of its prior problems.

This understanding of 21 U.S.C. § 360k(a) is confirmed by the FDA's preemption regulations, which are entitled to substantial deference. *Hillsborough County*, 471 U.S. at 713. They provide that preemption may occur only

> when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act....

21 C.F.R. § 808.1(d). Under this regulation, for there to be preemption, there must be federal requirements specific to

pacemaker leads that address the same subject matters upon which the Lohrs' state-law suit is based.

The court of appeals held that the Lohrs' manufacturing-defect and failure-to-warn claims were preempted by the FDA's good manufacturing and prescription labeling guidelines, which apply to devices *generally*. Those holdings are at odds with the regulatory command that the federal requirement be applicable to a "particular device." *Accord* 21 C.F.R. § 808.1(d)(6)(ii); *see also Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)(federal regulation requiring a specific warning for tampons preempted common-law duty-to-warn claim, but not claims that device was defectively designed and manufactured, in absence of specific federal design or manufacturing requirements for tampons). Because pacemaker leads are not subject to any device-specific manufacturing or labeling specifications, they are not subject to any requirements that preempt the Lohrs' common-law claims based on manufacturing defects or a duty to warn.

III. Finally, even if the Lohrs' claims were held to be "requirements" that could trigger preemption under section 360k(a), those claims could still go forward if the state-law duties on which the suit is based did not contravene federal standards in those areas. This conclusion is required by the plain terms of section 360k(a), which preempt state requirements only if they are "different from, or in addition to" federal law, not if they apply the same substantive standards. *See also* 21 C.F.R. § 808.1(d)(2). Here, for instance, the Lohrs' manufacturing-defect claim could proceed based on the standards set out in the FDA's general manufacturing guidelines. *See* 21 C.F.R. Part 820.

ARGUMENT

Several important aspects of this Court's jurisprudence converge in this case. First, despite the supremacy of federal law whenever applicable, a party seeking preemption of state law bears a heavy burden. There is a strong presumption against preemption

that may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985); *see also Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991).

This presumption is even stronger where, as in this case, preemption would displace the historic power of the states to protect the health and safety of their citizens. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Moreover, where preemption of common-law claims would leave injured individuals without any state *or* federal remedy, which is the result sought by Medtronic here, this Court ascribes preemptive intent to Congress only in the most compelling circumstances. *English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). These basic precepts are not mere precedential idiosyncracies, but are deeply embedded in the "federal-state balance" fundamental to the constitutional plan. *Hillsborough County*, 471 U.S. at 717; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Thus, the "plain statement rule" of the Court's Supremacy Clause jurisprudence "is nothing more than an acknowledgement that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991).

Finally, in the preemption context, as in others, the views of an agency charged with administering a statutory scheme are entitled to substantial deference. *Hillsborough County*, 471 U.S. at 714-15 (*citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). Here, the MDA is accompanied by a considerable body of FDA regulations and other authoritative agency pronouncements which narrowly construe the MDA's preemptive effect and establish that the Lohrs' claims are not preempted.

I. THERE IS NO PREEMPTION OF DAMAGES CLAIMS UNDER THE MDA, AS EVIDENCED BY ITS LANGUAGE, HISTORY, AND PURPOSE.

With due regard for the foregoing principles, the ultimate touchstone of preemption analysis is congressional intent. *Hawaiian Airlines*, 114 S. Ct. at 2243. Thus, the question presented here is whether, in enacting the MDA, Congress intended to eliminate state-law damages claims of the sort brought by the Lohrs. In this regard, it is important to understand the breadth of Medtronic's position in this case. Medtronic argues not only that 21 U.S.C. § 360k(a) reaches some damages claims, but that marketing a device on the basis of substantial equivalence to a pre-MDA device preempts all common-law claims, including those based on negligence in device design and manufacture and on failure to warn of known hazards from use of the product. In effect, Medtronic argues that, in enacting a consumer protection statute, the 94th Congress simultaneously barred access to the tort system for patients injured by potentially life-threatening medical devices.

Congress, however, did not enact such a radical incursion into the common law of the 50 states. Taken together, the language of the MDA's preemption provision, 21 U.S.C. § 360k(a), other relevant provisions of the MDA, the statute's history and purpose, and the FDA's preemption regulations, demonstrate that the express preemption provision of section 360k(a) does not foreclose any state-law damages suits seeking compensation for injuries caused by medical devices.

A. 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims.

Analysis of congressional intent begins with the language of the MDA's preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a)(App. 1a). Although the word "requirement" was construed in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), to encompass common-law claims in the specific context of one of the preemption provisions at issue there, "requirement" as used in section 360k(a) was intended to preempt only positive state law, not common-law tort claims, because the context here is very different from that in *Cipollone*.

1. *Cipollone* interpreted the term "requirement" only in the context of the Public Health Cigarette Smoking Act of 1969 ("the 1969 Act"). Because it did not hold that "requirement" *must* include the common-law whenever it is used, *Cipollone* did not resolve the question whether the word "requirement" as used in the MDA covers damages actions. Indeed, as *Cipollone* noted in holding that there was no preemption of common-law claims under the Federal Cigarette Labeling and Advertising Act of 1965 (the 1969 Act's predecessor), "[t]here is no general, inherent conflict between [express] federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." 505 U.S. at 518. Thus, *Cipollone* recognized that Congress can, and often does, expressly preempt only state positive law.

"Language, of course, cannot be interpreted apart from context." *Smith v. United States*, 113 S. Ct. 2050, 2054 (1993); *see also Brown v. Gardner*, 115 S. Ct. 552, 555 (1994)("a word is known by the company it keeps")(*citing Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)). In section 360k(a), "requirement" appears three times. The latter two uses of the term are references to federal requirements and, therefore, must refer to requirements imposed pursuant to statute or regulation under the MDA. These two uses do not refer to damages remedies or to the common law, because they are not the kinds of "requirements" applicable to devices under federal law. *See Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1460-61 (9th Cir. 1995)(Reinhardt, J., concurring); *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 209-10, 204 Ill. Dec. 744 (Ill. App. 1994); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 926 (1995).

The first use of "requirement" in section 360k(a), on which Medtronic relies, refers to the actions of states and their political subdivisions that are candidates for preemption under the MDA. The term is not modified in any way to distinguish it from the latter two uses, nor does it contain any embellishment or reference to damages actions or to the common law. Thus, the first use of "requirement" can include common-law damages actions only if it means something different from the subsequent uses of that term in the very same sentence.

However, there "is no reason to believe that Congress meant the term [requirement] to mean one thing" in the first part of section 360k(a) "but to mean something else altogether" the next two times it appears. *Comm'r v. Lundy*, 116 S. Ct. 647, 655 (1996). To the contrary, "the interrelationship and close proximity of these provisions ... 'present a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.'" *Id.* (*quoting Sullivan v. Stroop*, 496 U.S. 478, 484

(1990)(internal quotations and case citations omitted)); *see also, e.g., United States Department of Treasury v. Fabe*, 113 S. Ct. 2202, 2215 (1993) (Scalia, J., dissenting) (referring to foregoing principle as "basic rule of statutory construction").

These multiple uses of the word "requirement" in section 360k(a) sharply differentiate this case from *Cipollone*. There, "requirement" was used only once: "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 505 U.S. at 515 (quoting relevant statutory language). The use of "requirement" thus referred to the totality of "State law," which reasonably may include common law and which was critical to the *Cipollone* plurality's holding that some common-law claims were within the statute's preemptive reach. *Id.* at 522-23. Further, the 1969 Act made no mention at all of *federal* "requirements." Instead, it used *different* nomenclature—"labeled in conformity with the provisions of this Act"—to refer to the means by which the 1969 Act has preemptive effect. *Id.* at 515. Here, by contrast, the language of section 360k(a) does not target for preemption the totality of "State law," and, as explained above, this very provision uses "requirement" twice to refer only to federal positive law.

2. Under section 360k(a), only state requirements "with respect to a device" are candidates for preemption. This language also demonstrates that preemption under section 360k(a) is limited to state positive law. The duties under which tort plaintiffs seek compensation are not duties "with respect to a device," but rather are general obligations concerning the conduct of persons who manufacture and sell all types of products. For instance, the Lohrs seek compensation under common-law duties that obligate all manufacturers to design and manufacture their products with due care and to warn of their products' dangers. Even if those duties

were "requirements" in some sense, they are not requirements "with respect to a device" under section 360k(a).

On the other hand, the positive-law requirements to which section 360k(a) is directed are, in fact, requirements "with respect to a device." For example, a Florida statute requires that specific labeling appear on hearing-aid packages before the hearing aid may be sold. *See Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981). That requirement "with respect to a device" properly raised a preemption question because of its potential conflict with the FDA's hearing-aid labeling regulations. *See* 21 C.F.R. § 801.420; *see also* 21 C.F.R. §§ 808.53-.101 (governing status of similar positive state-law requirements under section 360k(a)).

This contrast between positive-law requirements "with respect to a device" and general common-law duties underscores a fundamental difference between the purposes of the two regimes. Like the Florida statute, a "requirement with respect to a device" obligates the seller to take a particular action concerning the device, for instance, to label the device in a particular manner or to manufacture it to certain specifications. If the seller does not satisfy the requirement, it cannot sell the device. Like the Lohrs' claims here, however, common-law claims do not require manufacturers to take any action with respect to a device. Thus, if the Lohrs prevail at trial, Medtronic will be obligated only to compensate the Lohrs. At some point, tort verdicts in cases involving Medtronic's 4011 lead may prompt the company to take some action with "respect to [the] device," but those verdicts will not *require* Medtronic to do so. This distinction drawn by section 360k(a) between positive law and common law reflects what, as noted earlier, the plurality recognized in *Cipollone*: "There is no general, inherent conflict between [express] federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." 505 U.S. at 518. *See Kennedy*, 67 F.3d at 1459.

The FDA has interpreted section 360k(a) in the same manner. In promulgating its preemption regulations, the agency stated that many state statutes "are not requirements 'with respect to a device' within the meaning of [section 360k(a)] because they generally pertain either to persons who manufacture devices or distribute devices...,and not directly to devices. In order for a State provision to be a requirement with respect to a device within the meaning of [section 360k(a)]—and thereby a candidate for preemption—it must relate to the device itself." 43 Fed. Reg. 18661, 18663 (May 2, 1978). *Cf.* 21 C.F.R. § 808.1(d)(no preemption under section 360k(a) of requirements of general applicability that apply to other products in addition to devices, such as uniform commercial code and unfair trade practices statutes); *see also Mulligan v. Pfizer*, 850 F. Supp. 633, 636 (S.D. Ohio 1994)(rejecting preemption of generally applicable common-law rules, contrasted with specific Ohio statute with respect to hearing aids).[4]

Because common-law duties such as those relied on by the Lohrs are not requirements with respect to a device, they are not preempted under section 360k(a).

3. Finally, section 360k(a) states that "[n]o State or political subdivision of a State may establish or continue in effect" certain

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[4] Accordingly, in a 1984 advisory opinion, the FDA rejected the preemption holding in *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177 (D. Mass. 1982), where the plaintiff sought a warning to Dalkon Shield users under Massachusetts common law. The advisory opinion—which is binding on the agency, *see* 21 C.F.R. § 10.85(e)—stated that "the act preempts only State and local requirements that directly and specifically relate to devices." Letter From Joseph P. Hile, Associate Commissioner for Regulatory Affairs, FDA, to National Women's Health Network (Mar. 8, 1984), App. 12a-13a. As the advisory opinion concluded, "[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of [21 U.S.C. § 360k(a)]."

device "requirements." Construing an award of damages to a tort plaintiff as "establishing or continuing in effect" a device requirement is at odds with this Court's oft-stated "assum[ption] 'that the legislative purpose is expressed by the ordinary meaning of the words used.'" *American Tobacco Co. v. Patterson*, 456 U.S. 63, 68 (1982)(*quoting Richards v. United States*, 369 U.S. 1, 9 (1962)); *see Haudrich*, 642 N.E.2d at 210. That "ordinary meaning" is confirmed in two respects.

First, in 1976, when the MDA was enacted, Congress was aware that states might "establish" programs to regulate medical devices, since some states had already done so. *House Report*, at 45. Thus, it is reasonable to assume that section 360k(a)'s reference to the "establishment" of device "requirements" meant the enactment of state medical device programs. At the same time, the duties relied on by tort claimants are general duties under the common law that had been "established" over hundreds of years. Thus, section 360k(a)'s limited prohibition on the future "establishment" of device requirements simply could not have been a reference to common-law duties.

Second, while a post-1976 jury award in a device case would represent confirmation of a pre-existing common-law duty—for instance, the duty to act non-negligently—only an inept grammarian would describe an award of damages in a tort case as "continuing in effect [a requirement] with respect to a device." On the other hand, it is common parlance to say that a previously-"established" statute or regulation remains in force or "continues in effect."[5]

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[5] The FDA's preemption regulations, discussed in greater detail *infra* at 25-27, describe in considerable detail whether, and in what circumstances, specific types of state and local statutes, regulations, and ordinances are preempted under section 360k(a). Those regulations do not mention damages remedies, providing further confirmation that the MDA was not intended to affect such remedies. *See* 21 C.F.R. §§

(continued...)

* * *

In sum, the rule that intent to preempt be "clear and manifest" and the related presumption against preemption applies not only to the existence of preemption, but also to its scope. *E.g., New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). Here, the language of section 360k(a) taken as a whole falls far short of the requisite plain statement and demonstrates that common-law claims are not preempted.[6]

B. Other Provisions Of The MDA Confirm That 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims.

1. The existence of subsection (b) of 21 U.S.C. § 360k further manifests Congress' understanding that subsection (a) does not preempt damages claims. Subsection (b) permits states to seek exemptions from the FDA for their device laws that would otherwise be preempted under subsection (a). The language of subsection (b) parallels that of subsection (a) and allows a "State or political subdivision" to exclude from preemption state "requirements" that are "applicable to a device for human use."

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[5](...continued)
808.1(d)(1)(state electrical codes, uniform commercial codes, and state unfair trade practice statutes), 808.1(d)(3)(state and local licensing and certification provisions), 808.1(d)(6)(state and local device enforcement provisions, and misbranding and adulteration statutes), 808.1(d)(8)(state and local provisions for raising revenue or fees); *see also* App. 14a (Letter from Chief of FDA's Regulatory Staff stating that, in the FDA's view, product liability law is not preempted by section 360k(a)).

[6] While section 360k(a) does not preempt any damages claims, we acknowledge the possibility that a state tort action against a medical device manufacturer could be preempted in certain limited circumstances based on conflict preemption principles. *See Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487-88 (1995).

See App. 1a-2a. In other words, subsection (b) allows the FDA to grant exemptions for any type of requirement that may be preempted under subsection (a).

Although subsections (a) and (b) apply to the same "requirements," the statutory language, the FDA's preemption regulations, and common sense make clear that subsection (b) does not include judgments in tort actions. First, it is difficult to imagine the basis for a state to obtain an exemption for a damages action in light of the relevant statutory criteria: that the state requirement be (1) more stringent than the federal requirement, or (2) required by "compelling local conditions." 21 U.S.C. § 360k(b). Without considering the evidence advanced by particular tort plaintiffs or reviewing jury instructions in hundreds of cases, it would be infeasible, if not impossible, for a state to seek a blanket exemption for its common law on the ground that it was "more stringent" than federal law. Furthermore, it makes little sense to say that providing compensation to medical device victims is "compell[ed] by local conditions," rather than by a state's general interest in assuring that its citizens have remedies for their injuries.

Nor could Congress have expected states to petition the FDA for exemptions for individual plaintiffs on a case-by-case basis. As one court put it, "if the term 'requirement' were interpreted so as to include tort law, the exemption provision [of § 360k(b)] would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?" *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *accord Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1989) (*dicta*); *cf. New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795, 813-14 (1978)(existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)). *See also* 21 C.F.R. § 808.5(b)(2)(indicating that state requirements are not eligible for exemption from preemption unless they have been "issued in final

form," which, when applied to tort claims, would be after final judgment).

In short, the state-law "requirements" referred to in sections 360k(a) and 360k(b) are co-extensive, and plainly state-law "requirements" under subsection (b) cannot rationally be construed to include damages claims. Thus, interpreting section 360k(a) "requirements" to include damage claims would be at odds with the canon of statutory construction that repeated uses of the same word in the same statute—here, in the very next subsection—should be accorded the same meaning. *See supra* at 17-19.

The FDA is of the same view. The agency's regulations implementing section 360k(b)—which are entitled to deference, *Hillsborough County*, 471 U.S. at 714-15—begin by stating that a "State or political subdivision may apply . . . for an exemption from any requirement it has *enacted* and that is preempted...." 21 C.F.R. § 808.20(a)(emphasis added)(App. 7a-9a). Similarly, the FDA requires state and local governments to submit "any *statute, rule, regulation or ordinance*" with respect to each "requirement" for which an exemption is sought. *Id.* (emphasis added)(App. 5a). All applications seeking exemption from preemption must identify the "title of the chief administrative officers of the State or local agency that has primary responsibility for administration of the requirement," 21 C.F.R. § 808.20(c)(1), which would be nonsensical with respect to damages claims since they are not "administered" by state or local "agenc[ies]." *See also* 21 C.F.R. § 808.1(d)(6)(ii)(in deciding whether state requirement is preempted in first instance, "the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the *statute*...")(emphasis added). Thus, the FDA has construed "requirement" under both subsections (a) and (b) identically and

in neither context has it included jury awards or common-law claims.[7]

The FDA has also encouraged state and local governments to obtain the agency's views on the MDA's preemptive scope before enacting new device laws. As the FDA put it, an "advisory opinion might be sought or issued when a State or local government is contemplating the issuance of a *statute or regulation*. In such cases, the advisory opinion could address the question of whether the *rule or regulation* as proposed would be preempted under section" 360k(a). 42 Fed. Reg. at 30385 (emphasis added); *see also id.* (making references to state requirements as "statutes," "regulations," "ordinances," and "relevant background material including legislative histories, hearing reports, and similar material"). In addition, the FDA has indicated that a state "requirement" is not "eligible for exemption from preemption" unless it has been "issued in final form." 21 C.F.R. § 808.5(b)(2) (App. 7a). Only regulations and ordinances and similar enactments, not common-law duties, are "issued in

[7] Several courts have incorrectly assumed that state tort law can be preempted because of an FDA regulation stating that a "court decision" may be subject to preemption under section 360k(a). 21 C.F.R. § 808.1(b); *see, e.g., Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992). However, the term "court decision," read in context, refers to judicial decrees enforcing or interpreting state positive law. *See Kennedy*, 67 F.3d at 1461-62 (Reinhardt, J., concurring). In commentary issued when it proposed 21 C.F.R. § 808.1(b), the FDA stated that, in considering requests for exemption, it "must know whether the statute, rule, or regulation has been subject to judicial or administrative interpretations that give it legal meanings in the State or political subdivision that are not readily apparent from the face of the document"). 42 Fed. Reg. 30383, 30385 (June 14, 1977); *accord* 43 Fed. Reg. 18661, 18663 (May 2, 1978). Thus, in requesting that states submit any relevant "statute, rule, regulation, or ordinance," the FDA's regulations explain that "[i]f the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall" submit copies of such interpretations. 21 C.F.R. § 808.20(c)(1); *see also id.* § 808.20(d).

final form." Thus, the FDA's regulations regarding section 360k(b) provide further confirmation that the term "requirement" as used throughout section 360k was not intended to cover damages claims. *See Rake v. Wade*, 113 S. Ct. 2187, 2193 (1993)("statutory terms are often clarified by the remainder of the statutory scheme--because the same terminology is used elsewhere in a context that makes [its] meaning clear").[8]

2. Subsection (d) of 21 U.S.C. § 360h also confirms the Lohrs' understanding of section 360k(a). Under section 360h, the FDA has the power to notify health professionals and the public of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds with respect to devices that pose such risks. "Of vast significance" to the preemption analysis, *Mulligan*, 850 F. Supp. at 636, is subsection (d), entitled "Effect on Other Liability." That subsection provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

[8] This reading of section 360k(b) is further substantiated by the fact that, although the states have sought exemptions from preemption in a series of regulatory proceedings before the FDA, 45 Fed. Reg. 67321-67338 (Oct. 10, 1980); *see* 21 C.F.R. §§ 808.53-.101, to our knowledge, *no* state has *ever* sought an exemption for jury awards or common-law duties. Indeed, many states have indicated their belief that common-law duties are not preempted by section 360k(a). *See* Brief of Alabama *et al.* in Support of Petition for Writ of Certiorari in *King v. Collagen Corp.*, No. 92-1979 (U.S. filed Aug. 18, 1993) (*amicus* brief signed by 28 state attorneys general urging review by this Court on ground that MDA preemption does not reach common-law claims); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 927.

Thus, section 360h(d) "specifically contemplates state law liability and damages" against manufacturers of medical devices, even after the FDA issues an order under section 360h. *Mulligan*, 850 F. Supp. at 636. Considered in conjunction with the statute's other provisions, the FDA's regulations, and the presumption against preemption, section 360h(d) is powerful evidence that the statute contemplated that state-law damages actions would coexist with MDA regulation. *Id.* As the Court observed in *Silkwood* in a related context, "the only congressional discussion concerning the relationship between the ... [statute] and state tort remedies indicates that Congress assumed that such remedies would be available." 464 U.S. at 251.

C. The Purpose And History Of The MDA Confirm That Damages Claims Are Not Preempted Under Section 360k(a).

The MDA's purpose and history also demonstrate that section 360k(a) preempts only positive state-law enactments. The MDA was passed "to protect the public health by amending the Federal Food, Drug, & Cosmetic Act to assure the safety and effectiveness of medical devices." Conference Report, H.R. Rep. 1090, 94th Cong. 2d Sess. 1 (1976). The Senate Report directly traced the Act's origins to the Dalkon Shield disaster:

> On January 28, 1975, the Health Subcommittee conducted a hearing which once again underlined the urgency of enacting medical device legislation. The hearing focused on the Dalkon shield, an IUD which was used by two million American women, and hundreds of thousands of women overseas, before the very significant health hazards of the device became known. All witnesses before the Committee, including the Commissioner of the Food and Drug Administration, testified that many of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation, as provided in the reported bill, had been in effect when the Dalkon shield was developed.

S. Rep. 33, 94th Cong., 1st Sess. 1-2, *reprinted in* 1976 U.S.C.C.A.N. 1070-72. As the bill's sponsor stated on the Senate floor, the focus of the MDA is on consumer protection: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975) (Sen. Kennedy).

Prior to enactment of the MDA, individuals could and did seek redress for injuries caused by medical devices through state-law damages actions. *House Report*, at 8. Congress' concern with the injuries caused by the Dalkon Shield surely did not impel it to *decrease* the remedies available to injured device users. In fact, Congress was aware of the important function played by the many suits brought against the Dalkon Shield's manufacturer. The House Committee that sponsored the legislation cited these suits as evidence of the enormity of the public health tragedy that could have been avoided had effective federal regulation been in place. *House Report*, at 8; *see also* S. Rep. 33, 94th Cong., 1st Sess. 1-2, *reprinted in* 1976 U.S.C.C.A.N. 1070-71. Having acknowledged the role of the civil justice system both in bringing the Dalkon Shield problem to light and in compensating the victims, Congress surely would not, in the same breath, have "remove[d] all means of judicial recourse" for the victims of such future calamities without a word to that effect. *See Silkwood*, 464 U.S. at 251.[9]

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[9] This point was well put by the Illinois Court of Appeals in *Haudrich v. Howmedica, Inc.*, 642 N.E.2d at 211 (citations omitted):

> [T]he primary purpose of the 1976 Medical Device Amendments was "to assure the reasonable safety and

(continued...)

Moreover, while the legislative history mentions nothing about preemption of damages claims, it *does* say something about the types of state law that *are* preempted. The House Report states that once a particular MDA requirement was in place, that requirement would preempt corresponding statutory provisions "governing *regulation* of devices by States and localities." House Report, at 45. The Report specifically mentions the 1970 California medical device statute. *Id.* The committee's reference to the California statute and similar enactments as state *regulation* is significant because *Cipollone* emphasized repeatedly that "the term 'regulation' most naturally refers to positive enactments, not to common-law remedies." 505 U.S. at 519; *see also id.* at 523 (same).

The legislative history's silence on preemption of damages remedies and its concomitant discussion of the potential for preemption of state regulatory programs take on even greater significance in light of this Court's precedents, which not only establish a presumption against preemption, but also require unmistakable evidence of preemptive intent to abolish common-law remedies where federal law provides no damages remedy. *See, e.g., Silkwood*, 464 U.S. at 251. Here, the MDA contains no express private right of action for damages, and courts are in agreement that there is no implied right of action under the Food,

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[9](...continued)
effectiveness of medical devices intended for human use." If safety was Congress' primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation in the entire country with the same statute it passed to promote safety. It would be stranger still for Congress to take such dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years. Yet the debate and Congressional record are barren of any indication that Congress intended to preempt court decisions by passing the 1976 Medical Device Amendments.

Drug, and Cosmetic Act, of which the MDA is a part. *See Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995)(reviewing case law). It would be inimical to this Court's Supremacy Clause jurisprudence to hold, as Medtronic urges, that Congress deprived consumers of *any* means of obtaining compensation for their injuries, where the statute makes no mention of preemption of common-law claims and where nothing in the legislative history so much as hints at such a drastic result.[10]

Finally, in stark contrast to recent lower court rulings that section 360k(a) preempts an array of common-law claims, no court came to such a conclusion for 15 years after the MDA's enactment. In the MDA's early years, the states obtained the FDA's views on whether their medical device statutes and regulations were preempted, *see, e.g.*, 45 Fed. Reg. 67321-67338, while the tort system continued unaffected. *E.g., Tetuan v. A.H. Robins, Co.*, 738 P.2d 1210 (Kan. 1987). Case law construing 21 U.S.C. § 360k concerned the MDA's preemptive effect on positive law, with most courts holding that even those regulatory efforts were not preempted in the absence of specific federal regulations on the same subject as the state regulation. *See, e.g., Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild*, 384 A.2d 795.

As late as 1989, the only serious question regarding preemption of damages actions was whether, in light of a specific FDA-mandated warning label for tampon packaging, tort claimants harmed by defective tampons could maintain suit on the ground that the warning was inadequate. *Compare, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), *with Callan*, 709 F. Supp. 662. Not until 1992 did any appellate court rule that

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[10] *See also* Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 924 & n.130 ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages because 'a common law right of action [already] exists'")(quoting legislative history).

preemption occurred merely because the defendant marketed a device through FDA procedures, *e.g.*, *Slater*, 961 F.2d 1330; *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), or that the MDA's general controls—which are applicable to all devices—had preemptive effect on garden-variety negligence and strict liability claims. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994).[11]

While this history did not, of course, inform the 94th Congress that enacted the MDA, it is nonetheless significant to the question now before the Court. Since statutes are to be interpreted according to their "ordinary meaning," *American Tobacco Co.*, 456 U.S. at 68, and preemption exists only where that is Congress' "clear and manifest" intent, *Hillsborough County*, 471 U.S. at 715, then surely if section 360k(a)'s purpose was comprehensive "tort reform," that purpose would not have taken so long to emerge. To the contrary, for 15 years the MDA was recognized

[11] One example of the post-1976 vitality of the tort system for those injured by medical devices is the tragedy involving the Shiley convexo-concave heart valve, a device given premarket approval by the FDA in 1979. Hundreds of Shiley heart valve patients have died because manufacturing and design defects make the valve prone to fracture. *See generally The Bjork-Shiley Heart Valve: "Earn As You Learn,"* Staff Report of the Subcommittee on Oversight and Investigations of the Energy and Commerce Committee of the U.S. House of Representatives, 101st Cong., 2d Sess., Comm. Print 101-R (Feb. 1990). Despite the valve's PMA, "hundreds of lawsuits" were brought during the 1980's, which were not dismissed on preemption grounds, leading to very substantial settlements. *In re Pfizer Securities Litig.*, 1990 U.S. Dist. Lexis 17409, *5 (S.D.N.Y. Dec. 21, 1990). Indeed, as late as 1992, Pfizer, Inc., Shiley's parent, entered into a class action settlement which, among other things, guaranteed $500,000 to $2,000,000 to fracture victims and their survivors. *Bowling v. Pfizer*, 143 F.R.D. 141, 150 (S.D. Ohio 1992), *appeal dismissed*, 14 F.3d 600 (6th Cir. 1993), *cert. denied*, 115 S. Ct. 294 (1994). It was not until 1993 that a reported decision appeared preempting any of the many lawsuits involving the Shiley valve. *Kemp v. Pfizer*, 835 F. Supp. 1015, 1020-21 (E.D. Mich. 1993), *appeal pending*, No. 94-1502 (6th Cir.).

for precisely what it was—much-needed consumer protection legislation, with a modest preemption provision enacted to override positive state law in particular circumstances.[12]

* * *

Statutory interpretation requires more than an arid focus on one word or phrase in isolation. As Learned Hand put it more than 60 years ago, "the meaning of a sentence may be more than that of the separate words, as a melody is more than the notes, and no degree of particularity can ever obviate recourse to the setting in which all appear, and which all collectively create." *Helvering v. Gregory*, 69 F.2d 809, 810-11 (2d Cir. 1934), *aff'd*, 293 U.S. 465 (1935). In keeping with that view, the task here demands that the words of section 360k(a) be interpreted together and in the context of the statute as a whole, and with deference to the views of the agency charged with its administration. Seen from that perspective, section 360k(a) does not include damages claims, and

[12] The current Congress also apparently believes that the MDA does not preempt common-law claims. The House of Representatives passed a bill in 1995 that, among other things, would eliminate punitive, but not compensatory, damages recoverable against medical device manufacturers in cases where the device received FDA approval. *See* H.R. 956, 104th Cong., 1st Sess. § 201(f)(1995)(reprinted and debated in 141 Cong. Rec. H2941-H2948)(Mar. 9, 1995)); 141 Cong. Rec. H3027 (Mar. 10, 1995)(passed). Similar legislation has been considered several times before, beginning as early as 1977. *See* Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 940-42 & nn.185-189; *see also, e.g.*, S. 687, 103d Cong., 1st Sess. § 203(b)(2)(A)(1993). These provisions would not merely be superfluous if the MDA had already eliminated common-law claims, but would substantially *increase* the remedies available to tort victims in bills that were intended to have precisely the opposite effect. The 1995 bill also provides a limit of $250,000 on noneconomic damages, such as those for pain and suffering and emotional distress, in "any health care liability action," defined to include actions against medical device manufacturers. H.R. 956, § 203. That provision also would be superfluous if Congress had eliminated tort liability against medical device manufacturers in 1976.

the Eleventh Circuit's decision upholding Medtronic's preemption defense should be reversed.

II. EVEN IF SECTION 360k(a) PREEMPTS SOME DAMAGES CLAIMS, IT DOES NOT DO SO IN THIS CASE.

A. The 510(k) Notification Process Does Not Impose A Federal Requirement That Preempts The Lohrs' Claims.

The court of appeals correctly rejected Medtronic's argument that the 510(k) notification procedure establishes a preemptive safety and effectiveness "requirement applicable ... to" the Model 4011. Pet. App. 27a. As noted earlier, in October 1982, Medtronic notified the FDA that its Model 4011 pacemaker lead was substantially equivalent to a pre-MDA device, which gave Medtronic the right to market the product 90 days thereafter. App. 10a; *see* 21 U.S.C. § 360(k)(1982).[13]

At that time, "substantial equivalence" was not defined by statute, and the FDA required only that the manufacturer's 510(k) notification include basic information directed toward showing the device's similarity to a predicate device. 21 C.F.R. § 807.87 (1982). In 1990, Congress defined "substantial equivalence." Pub. L. No. 101-629, § 12, 104 Stat. 4523 (1990)(codified at 21 U.S.C. § 360j(i)(1)); *see also* 57 Fed. Reg. 58403 (1992)(codified at 21 C.F.R. § 807.100). Under that definition, a manufacturer need only show that the device has the same intended uses and technological characteristics as the predicate device, regardless of the predicate device's safety and effectiveness. 21 C.F.R. § 807.100(b)(1). And even if the device does *not* share the same

[13] Since 1992, the FDA has forbidden the marketing of 510(k) products until it has determined that the device is substantially equivalent. 57 Fed. Reg. 58403 (Dec. 10, 1992)(codified at 21 C.F.R. § 807.100(a)(4)). In 1982, not even this was required.

technological characteristics as the predicate device, it may *still* be deemed substantially equivalent, if the manufacturer can show that the device is equivalent in safety and effectiveness to the predicate device (which itself was not reviewed for safety and effectiveness). *Id.* § 807.100(b)(2).[14]

Therefore, at the time the Model 4011 was marketed, Medtronic's only obligation was to submit a notification explaining the basis for its claim of substantial equivalence to a pre-MDA device. That action alone allowed Medtronic to market the device 90 days later. But even assuming that the 1990 statutory definition had been applied to the Model 4011 when it entered the market in 1982, and assuming further that the lead did *not* share the same technological characteristics as its predecessors (which cannot be determined from the record), the device entered the market simply because the FDA believed that the device was neither less safe nor less effective than a "grandfathered" device, which itself had never been reviewed for safety and effectiveness. Thus, even under these extremely generous assumptions, the 4011 lead was marketed and implanted in Lora Lohr without any agency review (much less approval) for safety and effectiveness, and without the imposition of any "requirements" specific to the pacemaker's manufacture or labeling. *See Larsen v. Pacesetters Systems, Inc.*, 837 P.2d 1273, 1281-82 (Haw. 1992).

For this reason, the FDA's letter issued in response to Medtronic's 510(k) notification made no mention of the device's safety or effectiveness nor of its manufacturing processes or its

[14] In 1990, Congress required manufacturers submitting Class III 510(k) notifications to submit summaries of, and citations to, all adverse safety and effectiveness data concerning the predicate device. Pub. L. No. 101-629, § 4(a), 104 Stat. 4515 (1990)(codified at 21 U.S.C. § 360c(f)(3)). This obligation does not impose any "requirements" on the design, manufacturing, or labeling of 510(k) products and does not, in any event, apply to Medtronic's October 1982 510(k) notification for the Model 4011 lead.

design, and it did not approve the device's labeling—the areas of potential overlap with the common-law duties invoked in the Lohrs' complaint. App. 10a; *see* Complaint, ¶ 6, R.E. 8. The FDA added that its letter "does not in any way denote official FDA approval of your device" and warned Medtronic about creating any "misleading" impression to the contrary. App. 11a. These admonitions, which track 21 C.F.R. § 807.97 (App. 2a), are fully consistent with an independent government study of the failures of Medtronic's pacemaker leads, including the Model 4011, which explained that the "substantial equivalence [process] ... does not require FDA to determine that any of these models are safe and effective—and FDA has not done so." *See* U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks are Still High* 1 (GAO/PEMD-92-20 Sept. 1992).[15]

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[15] Many other governmental reports and commentators have made the same point. *See, e.g.*, House Comm. on Energy and Commerce, *Less Than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administrations's Center for Devices and Radiological Health*, 103d Cong., 1st Sess., Committee Print 103-N, Report No. ISBN 0-16-040891-1, at 8-9 (May 1993)("Officials at the [FDA's] Center for Devices and Radiological Health point out that a finding of substantial equivalence does not represent, and should not be construed as, a statement of a device's safety and effectiveness. It means only that the device is substantially equivalent to a preamendment Class I, II, or III device [footnote omitted])"; Adler, *supra*, 43 Food Drug Cosm. L.J. at 516 ("[S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective"); Kahan, *supra*, 39 Food Drug Cosm. L.J. at 515-16 (1984)(same, but explaining that some 510(k) reviews are more extensive than others); U.S. Dept. of Health and Human Services, Office of Inspector Gen'l, *Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process*, ID No. A-15-89-00065, at 10-11 (continued...)

Significantly, in a regulatory pronouncement that is dispositive here, the FDA has announced that states are free to impose requirements for Class III 510(k) devices that, like the Model 4011 pacemaker lead, are not subject to a federal PMA regulation. Because some states required PMAs for certain devices, *see House Report*, at 45, during the FDA's promulgation of its preemption regulations, commenters asked whether state PMAs would be preempted even before the FDA had required a federal PMA for the particular device in question, *i.e.*, when the device was marketed solely under section 510(k). 43 Fed. Reg. at 18,664 (final rule). The FDA determined that users of Class III devices in states with PMA requirements should not have less protection from unsafe products while the MDA was being implemented than they had before the MDA's enactment. Thus, in the interim, a state could require its own PMA for Class III 510(k) devices:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully be marketed without approval of an application for premarket approval under ... 21 U.S.C. 351(f)(1)(A). Once these FDA requirements are established, different or additional State requirements are preempted.

Id.[16]

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[15](...continued)
(July 5, 1990)(510(k) process does not require submission of device specimen, verification of test results, or premarketing manufacturing inspections, noting that "the 510(k) review process is not intended for determining premarket *approval*")(emphasis in original).

[16] Subsequently, the FDA ruled that California's requirement that certain Class III devices undergo PMA would not be preempted until the FDA required a PMA for the particular device in question. 45 Fed. Reg. (continued...)

As the FDA explained in its November 1982 substantial equivalence letter, Medtronic's Class III pacemaker leads "will be required to undergo premarket approval *at some time in the future.*" App. 10a. But that date has not arrived. 21 C.F.R. § 870.3680(b), (c). Thus, even today, any state may require that pacemaker leads undergo PMA regulation, including ultimate marketing approval (*or disapproval*). Put another way, because state-based PMAs are not preempted for Class III devices subject only to 510(k) regulation (such as Medtronic's pacemaker leads), the states may decide which of those devices may be sold in their states. *See Myrick*, 115 S. Ct. at 1487 (1995)(no preemption of state claim because no federal standard in place). In light of this fact, it is difficult to conceive how the Lohrs' claims can be preempted: Those claims seek only compensation for injuries and stop far short of demanding the type of state-law PMA procedures specifically permitted by the FDA, which tell the manufacturer whether it can market its product at all.

In summary, the 510(k) process does not result in "requirements" within the meaning of 21 U.S.C. § 360k(a). Therefore, claims premised on state-law duties properly to manufacture and to warn about a product are not preempted by the 510(k) process, even assuming that some common-law tort claims are within the ambit of section 360k(a).

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[16](...continued)
at 67323. Responding to comments which suggested that California PMAs should be preempted if the FDA had *proposed* that a Class III device be downclassified, the agency "disagree[d] with the comments' suggestion that the Federal law should preempt premarket approval for a [class III] device recommended for classification into class I or class II. The counterpart FDA requirement for such a device is not established until the date of final classification...." *Id.; accord* 43 Fed. Reg. at 18,664 (state-law performance standard for Class II device preempted only after FDA has established performance standard for that particular device).

B. No Other Federal Requirements Preempt Any Of The Lohrs' Claims.

1. In Order To Have Preemptive Effect Under Section 360k(a), Federal Requirements Must Be Device-Specific And Subject-Specific.

Section 360k(a) provides that there is no preemption unless there is a federal requirement specifically "applicable to the device," and the corresponding state law is "different from, or in addition to" that federal requirement. Thus, even assuming that section 360k(a) reaches damages actions, the Lohrs' claims are preempted by section 360k(a) only if there are federal requirements imposed specifically upon manufacturers of pacemaker leads, and only if those requirements apply to the features of those leads on which the Lohrs' claims are based.

Despite its holding that the section 510(k) notification process does not, in itself, have any preemptive effect, the court of appeals concluded that the Lohrs' duty-to-warn and manufacturing-defect claims were preempted by FDA labeling and good manufacturing guidelines that apply generally to medical devices. However, the proper preemption analysis—as reflected in the FDA's preemption regulations—demands a much closer fit between a federal "requirement" and the relevant state-law duty.

In defining what types of state and local requirements are subject to preemption, the FDA has stated that:

> State or local requirements are preempted *only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act*, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added)(App. 3a-4a). When it promulgated these regulations, FDA explained its interpretation of section 360k(a). Looking first to the words chosen by Congress—dictating that there be a pre-existing federal requirement "applicable *to the device*"—the agency found that device-specific federal rules must first be in place before any preemption can occur. 43 Fed. Reg. at 18662 (highlighting italicized statutory language). The FDA further explained:

> Thus, from a plain reading of section [360k] of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. ... [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling ..., which occurred when the new FDA hearing aid regulations took effect... . [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

Id.[17]

This insistence upon device-specific requirements for the same subject matter regulated by the state—which the FDA refers to as the need for "specific counterpart" requirements—is found throughout the FDA's regulations. For instance, the MDA does not preempt state registration or certification schemes for medical professionals simply because they "administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). If, however, the FDA

[17] *See also* 42 Fed. Reg. at 30385 (June 14, 1977)(proposed rule)("a preempting FDA requirement will become applicable to a device within the meaning of section [360k(a)] only after FDA takes a regulatory or administrative action involving the application of a particular requirement of the act to a particular device").

exercises its authority under the MDA to restrict the use of certain devices to particular health professionals, *see* 21 U.S.C. §§ 360j(e),(g), then the federal requirements control, but only to the extent that state and local regulations actually conflict with them. 21 C.F.R. § 808.1(d)(3). And of particular relevance to the Lohrs' duty-to-warn claim, states and localities may prohibit the manufacture of mislabeled devices unless the FDA has established a "specific labelling requirement for a specific device" which conflicts with the state or local requirement. *Id.* § 808.1(d)(6)(ii); *see also Cipollone*, 505 at 524-30 (claims based on alleged deficiencies in the specific warning required by Congress preempted, while claims not in specific conflict with the federal warning not preempted).

The FDA's regulation concluding that preemption occurs only when there is a device-specific federal regulation that is a "specific counterpart" to the state-law requirement is a "permissible construction" of section 360k(a) for two reasons. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). First, the statute directs that there be a federal requirement "applicable" to a device, which easily supports the FDA's demand for specific counterpart federal requirements. As the FDA explained when it promulgated its regulation, "[t]he phrase 'or in addition to, any requirement applicable under this Act to the device' means that an FDA requirement must exist before preemption can occur." 43 Fed. Reg. at 18662; *see Myrick*, 115 S. Ct. at 1487.

Second, the regulatory determination that federal requirements must be specific to a "particular device" is consistent with the statute's insistence that preemptive requirements relate to "*the* device" under section 360k(a), rather than to requirements that apply to devices generally. Thus, the FDA's demand for device-specific, subject-specific "requirements" under section 360k(a) is entitled to deference as the agency's reasonable

construction of the statute, and it is controlling here. *See Hillsborough County*, 471 U.S. at 714-15.

2. None Of The Lohrs' Claims Is The Subject Of Any Specific Federal Requirement.

In order to evaluate whether a particular claim is preempted, it is necessary to determine whether there is a device-specific counterpart federal requirement that is different from the corresponding state-law claim. *See Kennedy*, 67 F.3d at 1457-59; *Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 907 (D. Colo. 1994), *appeal pending*, No. 95-1085 (10th Cir.). Here, because there are no such specific federal requirements, the Lohrs' claims are not preempted. *See Myrick*, 115 S. Ct. at 1487 (no preemption of state-law tort claim based on failure to install anti-lock brakes, because no standard in place specifically concerning anti-lock brakes).

a. *The Duty-To-Warn Claim.* The Lohrs' duty-to-warn claim is based on the theory that Medtronic should have alerted doctors and patients to the previous failures of its pacemaker leads. There are no specific warning requirements applicable to pacemaker leads, in contrast, for instance, to hearing aids and tampons. 21 C.F.R. §§ 801.420, 801.430. Indeed, as explained earlier, device labeling is *never* approved in conjunction with a 510(k) notification (since all that is required is a finding of substantial equivalence to a pre-MDA device). Further, there is no evidence here that the labeling was even submitted by Medtronic to the FDA during the 510(k) notification process. *See generally* Declaration of Charles H. Swanson, R1-37, Ex. 1 (describing 510(k) submission, but not mentioning submission of labeling); *see also* U.S. General Accounting Office, *Medical Devices: FDA's 510(k) Operations Could Be Improved* 62 (GAO/PEMD-88-14 Aug. 1988)(one third of 510(k) applications contain no labeling at all).

As noted earlier, the FDA has specifically addressed the issue of when federal rules have preemptive effect, using the labeling of hearing aids as an example. The FDA stated that a state's labeling requirements for hearing aids would not be preempted *until the FDA's specific hearing-aid labeling requirements took effect*. 43 Fed. Reg. at 18,662; *accord* 21 C.F.R. § 808.1(d)(6)(ii). On the other hand, the general labeling rules are not device-specific; indeed, they do little more than tell manufacturers to list the device's indications, warnings, contraindications, and the like. *See* 21 C.F.R. § 801.109(c)). Therefore, the court of appeals' reliance on these general rules was erroneous. *See* Pet. App. 32a-33a. They have no preemptive effect on a state's labeling requirements applicable to specific aspects of a particular device, much less on common-law claims.

Thus, even if Congress intended some preemption of damages claims, the Lohrs' duty-to-warn claim is not preempted because there are no specific FDA-required warnings with respect to pacemakers or their leads. *See, e.g., Moore v. Kimberly-Clark*, 867 F.2d 243 (federal regulation requiring a specific warning for tampons preempted a common-law duty-to-warn claim, but not claims that the device was defectively designed and manufactured, in absence of specific federal design or manufacturing requirements for tampons).

b. *The Manufacturing-Defect Claim.* The same kind of analysis applies to the Lohrs' manufacturing-defect claim and results in the same finding of no preemption. According to the Eleventh Circuit, the FDA's general good manufacturing practice ("GMP") regulations preempt the manufacturing-defect claim. Pet. App. 30a. But as the FDA has explained, these regulations are "umbrella" guidelines "applicable to all finished device manufacturers [which] should not be so specific as to prescribe for each manufacturer the precise details of what it must do and how it must undertake to manufacture devices. Rather, the GMP regulation ... contain[s] general requirements in specific areas of

concern to all manufacturers...." 43 Fed. Reg. 31508 (July 21, 1978).

Far from being device-specific requirements, the GMPs are little more than common-sense standards for the production of any product. *See generally* 21 C.F.R. Part 820. For instance, the regulation regarding device packaging states that "[t]he device package and any shipping container for a device shall be designed and constructed to protect the device from alteration and damage during the customary conditions of processing, storage, handling, and distribution." 21 C.F.R. § 820.130. Similarly, the FDA's "contamination control" regulation states in its entirety that "[t]here shall be procedures designed to prevent contamination of equipment, components, or finished devices by rodenticides, insecticides, fungicides, fumigants, hazardous substances, and other cleaning and sanitizing substances. Such procedures shall be documented." *Id.* § 820.56(b); *see also, e.g., id.* § 820.56(d)("*Sewage and refuse disposal.* Sewage, trash, by-products, chemical effluents, and other refuse shall be disposed of in a timely, safe, and sanitary manner").

* * *

The ramifications of Medtronic's position warrant some discussion. Approximately 98 percent of all devices—whether Class I, Class II, or Class III—enter the market as substantial equivalents to pre-MDA devices. H.R. Rep. 808, *supra*, at 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. As the FDA informed Medtronic with respect to the Model 4011, these devices are subject only to the MDA's general controls. App. 10a. Thus, if Medtronic's expansive view of the preemptive effect of section 510(k) and the Act's general controls were accepted, the MDA would virtually eradicate state tort law as applied to medical devices. For instance, if the MDA's general manufacturing guidelines have preemptive effect, a patient bacterially infected by a Class I band-aid, *see* 21 C.F.R. § 880.5240, would be barred from obtaining state-law compensation. Similarly, under

Medtronic's view of the statute, if a fetal heart monitor, *id.* § 884.2600, failed to alert a physician to fetal distress because one of its components had been damaged as a result of the manufacturer's improper storage, an action for damages against the manufacturer would be preempted by the FDA manufacturing guidelines, even though they do nothing more than describe prudent manufacturing procedures applicable to any product. *E.g., id.* §§ 820.80, .81 (control of components).

However, these general federal regulatory controls on medical devices, upon which the court of appeals relied, do not establish "requirements" applicable to a "particular device" within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). To hold otherwise, would, under the guise of federal preemption, legislate a comprehensive abolition of state product liability law for medical devices that Congress did not debate and did not intend.

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED TO THE EXTENT THAT THEY RELY ON FEDERAL STANDARDS.

Even if the Lohrs' common-law claims alleging defective manufacture and failure to warn were held to be "requirements" sufficient to trigger preemption under section 360k(a), the Lohrs' claims could still go forward if the state-law duties under which compensation is sought did not contravene federal standards in those areas. The court of appeals held, however, that allowing a jury to award damages by reference to a federal standard would usurp the FDA's proper role. Pet. App. 13a.

The court of appeals' decision in this regard is flawed for several reasons. First, it is at odds with section 360k(a)'s plain language which—whatever its other limits—does not preempt state requirements unless they are "different from, or in addition to" an applicable federal requirement. *See* 21 C.F.R. § 808.1(d)(2)("substantially identical" state or local requirements not preempted). Thus, claims that seek only to enforce federal

standards should not be preempted under any circumstances. For instance, petitioners' manufacturing-defect claim under Florida common law, like many such claims, will be tried, at least in part, based on the failure of Medtronic to manufacture its device in conformance with its specifications, *see* Complaint, ¶ 6, R.E. 8, and could easily be submitted to the jury in a manner that tracks the highly generalized federal standards on that subject. *See* 21 C.F.R. §§ 820.160-.62. In that case, since the Lohrs' claim would support, not undermine, the relevant federal norm, there would be no reason for preemption to apply.

Second, under the court of appeals' reasoning, the states would retain the ability to enforce federal standards under their regulatory regimes, which would have a direct effect on manufacturer conduct. *See* 21 C.F.R. § 808.1(d)(6)(i); 45 Fed. Reg. at 67322. However, an award of damages based on state incorporation of federal standards would be preempted, even though its principal purpose would be to provide compensation, with the only effect on primary conduct, if any, being incidental and entirely consistent with federal standards. Thus, the court of appeals' reasoning would result in a preemption regime under which enforcement of state positive law would receive *more* protection from the incursions of federal law than would damages claims—a bizarre result since neither the statute nor its legislative history makes any mention of common-law preemption at all.

Finally, the obliteration of common-law remedies that go no further than federal law, like all of Medtronic's arguments, runs headlong into the presumption against preemption. This Court has been loathe to find preemption of state law without a clear statement by Congress, even in cases involving the use of state positive law to impose requirements that are the subject of comprehensive federal health and safety legislation. *Mortier*, 501 U.S. at 609-11; *Hillsborough County*, 471 U.S. at 713-16. In cases such as this, where preemption would mean that the Lohrs and thousands of others harmed by medical devices are without

any recompense for their injuries, the Court has been even more exacting in requiring that preemption appear unmistakably in the statutory text and has left it to Congress to enact the kind of sweeping immunity from liability that Medtronic seeks to obtain here by judicial decree.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed, and the case remanded with instructions that all of the Lohrs' claims may go forward.

Respectfully submitted,

ROBERT L. COWLES
DANIEL C. SHAUGNESSY
COWLES & SHAUGNESSY
Suite 901
233 East Bay Street
Jacksonville, FL 32202
(904) 359-9500

ROBERT F. SPOHRER
SPOHRER, WILNER & MAXWELL
444 East Duval Street
Jacksonville, FL 32202
(904) 354-8310

BRIAN WOLFMAN
(Counsel of Record)
ALLISON M. ZIEVE
ALAN B. MORRISON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, N.W.
Washington, D.C. 20009
(202) 588-1000

LAURENCE H. TRIBE
Hauser Hall 420
1475 Massachusetts Avenue
Cambridge, MA 02138
(617) 495-4621

Attorneys for Cross-Petitioners

March 1, 1996

APPENDIX

PRINCIPAL STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

Effect on Other Liability

Compliance with an order [to provide notification, repair, replacement, or reimbursement regarding an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

PRINCIPAL REGULATORY PROVISIONS INVOLVED

21 C.F.R. § 807.97 provides:

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

21 C.F.R. § 808.1 provides:

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements

applicable to medical devices under section 521 [21 U.S.C. § 360k] of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific

counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal requirements shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statues, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

21 C.F.R. § 808.5(b) provides in part:

(2) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations: . . .

A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in a final form. In such a case, the advisory opinion may indicate whether the proposed requirement would be preempted and, if it would be preempted, whether the Food and Drug Administration would propose to grant an exemption from preemption.

21 C.F.R. § 808.20 provides:

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr. Rockville, MD 20857. The outside wrapper of any

application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the

State or political division is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or materials showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any requirement which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.

OTHER RELEVANT MATERIALS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

November 30, 1982

Mr. Edward W. Numainville
Product Regulation Manager
Medtronic Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, Minnesota
55440

Ref: K822781/A -
Medtronic Models 4011 &
4511
Dated: October 20, 1982
Received: October 21, 1982
Regulatory Class: III

Dear Mr. Numainville:

We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This product has been placed into the regulatory class shown above by a final regulation published in the *Federal Register*. Class I devices are regulated by the general control provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices are those for which future performance standards will be developed; class III devices are those which will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the *Federal Register*. We suggest you subscribe to this publication so that you can convey your view to FDA if you desire. Also, the *Federal Register* will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you need further assistance on the labeling for your device, please contact the Office of Medical Devices, Division of Compliance (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
Robert G. Britain
Associate Director for
Device Evaluation
Office of Medical Devices
National Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included

in a requirement applicable to a device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to advice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National Women's Health Network, et. al.* v. *A.H. Robins Company, Inc.*, No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures